Remarks

Claims 1-19 are pending upon entry of this amendment. Claims 1 and 14 have been amended to correct grammatical errors. Claim 1 has also been amended to more clearly define a method of detecting osteoporosis in an individual. Support for this amendment can be found in the specification at least at bridging pages 26-27, lines 26-29 and lines 1-2. Applicants believe that it is proper for the present amendment to be entered since it places the application in condition for allowance. Alternatively, entry of this amendment is proper since it places the claims in better form for appeal, does not raise any new issues, and does not require further consideration or search.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 1-19 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

The test of enablement is whether one of ordinary skill in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Stephens,* 529 F.2d 1343, 199 U.S.P.Q. 659 (C.C.P.A. 1976). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 13321, 1332 (Fed. Cir. 1991); *Spectra-Physics, Inc. v. Coherent,*

Inc., 827 F.2d 1524, 3 U.S.P.Q.2d 1737 (Fed. Cir. 1987). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation (*M.I.T. v. A.B. Fortia*, 774 F.2d 1104 (Fed. Cir. 1985)).

Whether undue experimentation is needed is not based upon a single factor; it is a conclusion reached by weighing many factors. These factors have been summarized in *In re Wands*, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) and include, but are not limited to:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The relative skill of those in the art;

(7) The predictability or unpredictability of the art; and

(8) The breadth of the claims.

The M.P.E.P. explains that "[i]t is improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors while ignoring one or more of the others." Thus, a conclusion of nonenablement must be based on the evidence as a whole, as related to each of these factors (see M.P.E.P. § 2164.01 (a)).

The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." *Atlas Powder*

Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir.1984). **There is no requirement for examples.**

As the Board of Patent Appeals recently quoted in another case,

"Nevertheless, "[w]hen rejecting a claim under the enablement requirement of section 112," it is well settled that "the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)."

"Thus, the dispositive issue here is not whether appellants have established that the disclosure is broadly enabling for the scope of the claims, rather, the issue is whether the PTO has met its "initial burden of setting forth a reasonable explanation as to why" it is not."

The adequacy of a specification's description is not necessarily defeated by the need for some experimentation to determine the properties of a claimed product. *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F3d 956, 965-966 63 USPQ2d 1609, 1614 (Fed. Cir. 2002).

Claims 1-19 are enabled.

The specification discloses to one of ordinary skill in the art how to make and use the claimed method without undue experimentation. Claim 1 defines a method of detecting osteoporosis by (1) **obtaining a sample of bone-related tissue,** (2) assaying the concentration of

a marker selected from the group of infectious agents, factors produced by infectious agents, and heat shock proteins produced in response to an infectious agent, and (3) comparing the concentration of a marker from an individual with the concentration of said marker from a control individual who does or does not have osteoporosis.

Methods of obtaining a sample of bone related tissue or cells from an individual are well known in the art. A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q.2d 13321, 1332 (Fed. Cir. 1991); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 3 U.S.P.Q.2d 1737 (Fed. Cir. 1987). Methods of assaying the concentration of a marker are also well known in the art and are disclosed in the specification at least at page 8, lines 4-29, and at page 9, lines 1-12. Methods of comparing the concentration of a marker from an individual with the concentration of said marker from a control individual are well known in the art and are disclosed in the specification at least at page 11, lines 21-28, and at page 19, lines 19-21.

The specification discloses working examples of detecting osteoporosis by measuring bacteria, bacterial produced factors, and heat shock proteins. However, **no working examples are necessary**. The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). The examiner admits in the office action at page 3 lines, 15-17, that general methods to assay for infectious agents or factors produced by thereof are known. The claims define

obtaining a sample of **bone-related tissue** and measuring at least one of the markers selected from the group of infectious agents, factors produced by infectious agents, and heat shock proteins produced in response to an infectious agent. While measurement of these factors may require experimentation, one of skill in the art typically engages in such experimentation. Therefore, the specification discloses to one of ordinary skill in the art how to make and use the claimed method without undue experimentation. Therefore, claims 1-19, as amended, are enabled by the specification.

Rejection Under 35 U.S.C. § 103

Claims 1-6, 8, and 11 were rejected under 35 U.S.C. § 103(a) as obvious over Findlay (WO 00/13024) ("Findlay"), in view of Nair, Calcified Tissue International 64(3): 214-218 (1999) ("Nair"), or in view of Reddi, et al. Journal of Bone and Mineral Research 13(8): 1260-1266 (1998) ("Reddi"). Applicants respectfully traverse these rejections to the extent that they are applied to the claims as amended.

The Legal Standard

The U.S. Patent and Trademark Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177 (C.C.P.A. 1967), *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). In rejecting a claim under 35 U.S.C. § 103, the Examiner must establish a *prima facie* case that: (i) the prior art suggests the claimed invention; and (ii) the prior art indicates that the invention

would have a reasonable likelihood of success. *In re Dow Chemical Company*, 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988).

Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992). *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). This is not possible when the claimed invention achieves more than what any or all of the prior art references allegedly suggest, expressly or by reasonable implication. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680 16 USPQ2d 1430 (Fed. Cir. 1990).

The Prior Art

Findlay

Findlay discloses a method for a predictive assay that measures **internal** regulators of bone remodeling as a predictive measure for the **potential** onset of certain skeletal disorders. Findlay discloses a method that includes the steps of taking a sample of body tissue or body

fluid and measuring or estimating the level of a regulator of bone remodeling. Findlay discloses internal regulators of bone growth such as growth factors, cytokines, and associated proteins.

Nair

Nair discloses a study of molecular chaperones for activity in the murine calvarial bone resorption assay. Nair discloses that certain bacterial and mammalian molecular chaperones can stimulate bone resorption.

Reddi

Reddi discloses a study of bacterial chaperones for osteoclast formation. Reddi discloses that cpn60 from *E. coli* stimulates bone resorption and osteoclast formation in culture. Reddi also discloses that a protein on the surface of *Actinobacilus actinomycetemcomitans*, which causes periodontal disease, can stimulate bone resorption.

Analysis

To establish a *prima facie* case of obviousness, the references must disclose or suggest **all** of the claim limitations. Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992). *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). Findlay discloses a method of measuring **internal** regulators of bone resorption. Reddi and Nair disclose that mammalian and bacterial molecular chaperones can stimulate bone resorption. The claims in the present application define a method of detecting osteoporosis in an

individual that contain the steps of measuring infectious agents, factors produced by infectious agents, or **endogenous** factors that are **induced** by infectious agents. Findlay, Reddi, and Nair do not disclose a method of detecting osteoporosis in an individual that contains the steps of measuring **endogenous** factors that are altered in expression **due to infection**. Therefore, Findlay, Reddi, and Nair do not disclose or suggest all of the claim limitations defined in the present application.

In addition to disclosing each of the claimed element, there must be some suggestion to modify or combine the reference teachings. The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

Findlay discloses a method of measuring **internal** regulators of bone resorption, such as cytokines and growth factors for the purpose of predicting the onset of certain skeletal disorders. Reddi and Nair disclose that mammalian and bacterial molecular chaperones can stimulate bone resorption. There is no suggestion in Findlay, Reddi, and Nair, to modify or combine the references. The claims in the present application define a method of detecting osteoporosis in an individual that contain the steps of measuring infectious agents, factors produced by infectious agents, and **endogenous** factors that are **induced** by infectious agents. Findlay does not disclose or suggest a method of detecting causative factors of bone resorption such as endogenous factors that are altered in expression due to infection. Reddi and Nair do not disclose or suggest measuring endogenous factors, such as heat shock proteins, that are **induced by infection** to

detect osteoporosis in an individual. Since there is no suggestion or motivation to modify or combine the references, the claims defined in the present application are not obvious over Findlay in view of Nair or Reddi.

Since Findlay, Reddi, and Nair do not disclose all of the claim limitations defined in the present application, and there is no suggestion or motivation found in Findlay, Reddi, and Nair to combine the reference teachings, the subject matter of claims 1-19 is not obvious.

Allowance of claims 1-19 is respectfully solicited.

Respectfully submitted,

Patrea L. Pabst
Reg. No. 31,284

Date: October 1, 2004
PABST PATENT GROUP LLP
400 Colony Square, Suite 1200
1201 Peachtree Street
Atlanta, Georgia 30361
(404) 879-2151
(404) 879-2160 (Facsimile)